Before the
Federal Communication Commission **FCC 94-155**
Washington DC 20554

In the Matter of

Amendment of Part 18 to	)	
Remove Unnecessary Regulations	)	ET Docket No 92-255
Regarding Magnetic Resonance	)	RM-7903
Systems	)	

REPORT and ORDER

Adopted: June 13, 1994 **Released: July 13, 1994**

By the Commission: Commissioners Ness and Chong not participating.

INTRODUCTION

1. By this action, the Commission amends Part 18 of its rules to remove regulations that unnecessarily increase the amount of time and money required to bring new non-consumer, medical magnetic resonance (MR) systems to market. These systems are used by medical professionals to study the molecular structure of a patient for diagnostic and monitoring purposes. This action addresses a petition for rule making filed by the National Electrical Manufacturers Association.

BACKGROUND

2. Part 18 of the rules sets forth requirements designed to minimize the potential for interference to radio and TV services from industrial, scientific and medical (ISM) equipment.[1] Such equipment generates radio frequency (RF) energy in order to perform a non-communications related function. Common examples of consumer ISM equipment include microwave ovens and RF lighting devices. Examples of non-consumer ISM equipment include industrial heaters, RF stabilized arc welders and magnetic resonance equipment. Before ISM equipment can be marketed in the

[1] See 47 CFR Section 18.101, et seq.

United States, it must comply with the technical standards and equipment authorization procedures specified in Part 18.

3. On January 29, 1992, the National Electrical Manufacturers Association (NEMA) filed a petition for rule making requesting that Part 18 of the Commission's rules be amended to exempt medical MR systems from the Part 18 technical standards and authorization requirements.[2] Medical MR systems generate radio signals, typically in the HF or low VHF range, below 64 MHz, in order to produce images of body organs. NEMA stated that medical MR systems pose little risk of interference. It noted that MR systems must be capable of detecting very weak radio signals. Therefore, MR systems are shielded against outside radio noise. This same shielding prevents radiation of the radio signals generated by MR systems to the outside environment. NEMA stated that it was unaware of any reported instances of interference caused by MR systems. NEMA argued that the required testing is costly and disruptive because it must of necessity be performed in a hospital or health care facility. NEMA noted that in 1986, under similar circumstances, the Commission exempted medical ultrasonic equipment from Part 18 technical standards and authorization requirements.[3]

4. On November 4, 1992, we adopted a Notice of Proposed Rule Making (Notice) proposing to exempt MR systems from the Part 18 technical standards and authorization requirements.[4] In the Notice, we tentatively concluded that the cost of our technical standards and authorization requirements for MR systems were unwarranted given the low risk of interference.

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[2] See Petition for Rule Making of the Magnetic Resonance Section of the National Electrical Manufacturers Association, RM-7903. MR systems must currently comply with technical standards that limit the radio frequency energy that is radiated from the system or conducted onto the electrical power line. See 47 CFR. Sections 18.305 and 18.307. MR Systems are also subject to verification of compliance by the manufacturer. See 47 CFR Section 18.203(b). Under the verification requirement, the manufacturer must test the product, retain a copy of the test report and place a label on the product. See 47 CFR Section 2.902. Submittal of information to the Commission is required only upon request.

[3] See Report and Order, General Docket No. 85-303, 1 FCC Rcd 553 (1986).

[4] See Notice of Proposed Rule Making, ET Docket No. 92-255, 7 FCC Rcd 7945 (1992).

5. Six parties filed comments in response to the Notice;[5] NEMA filed the only reply comment. Except for Maximum Service Television, Inc. (MSTV), the commenting parties fully support our proposal regarding MR systems. In its comments, MSTV indicates that it does not oppose this proposal. However, MSTV expresses concern about the potential for an overall increase in noise in the television broadcast bands, and asks that we undertake a comprehensive examination of the issue of unintentional electromagnetic emissions that cause interference to broadcast services.

DISCUSSION

6. We continue to believe that the cost of our technical standards and equipment authorization requirements for medical MR systems are unwarranted given the low risk of interference. As discussed in the Notice, it appears that MR systems pose little risk of interference to radio communications because of the way they are designed and installed. It also appears that there are relatively few installations of MR systems (under 1000), and in the event that measures need to be taken to correct interference, the location of the MR systems are known.[6] Compliance with the technical standards and equipment authorization requirements of Part 18 are burdensome and costly for the manufacturers of MR systems. Given the low volume production of medical MR systems, this can significantly affect the unit cost of each system, contributing to the increasing costs of medical care.

7. We agree with NEMA that the circumstances presented here are similar to those that led us earlier to exempt non-consumer medical ultrasonic equipment from Part 18 technical standards and equipment authorization requirements. We are unaware of any interference that has resulted from the medical ultrasonic equipment exemption, and do not expect interference to result from the similar exemption of MR systems.

8. We appreciate MSTV's concerns about the noise levels in the TV bands. However, we have no evidence or other information suggesting that the changes proposed in the Notice are likely to raise those noise levels or, more importantly, to cause

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[5] Comments were filed by Advanced NMR Systems, Inc.; American College of Radiology; General Electric Medical Systems; Hitachi Medical Systems of America, Inc.; Maximum Service Television, Inc.; and Siemens.

[6] U.S. Food and Drug Administration rules require manufacturers to maintain a product locator file for MR systems.

interference to television reception.[7] Regarding MSTV's request that we take a comprehensive look at television interference in general, such a study is beyond the scope of this proceeding.

9. Accordingly, we are amending Sections 18.107 and 18.121 of our rules as proposed in the Notice. We will continue to apply the requirement of Section 18.111(b) that operators of medical MR systems correct any harmful interference that may occur.[8]

PROCEDURAL MATTERS

10. Final Regulatory Analysis. Pursuant to the Regulatory Flexibility Act of 1980, the Commission's final analysis is as follows:

I. Need and purpose of this action:

The rule changes adopted in this Report and Order exempt MR systems from the technical standards and authorization requirements in Part 18. Given the small risk of interference being caused to communications by MR systems, compliance with the existing technical standards and equipment authorization requirements is unnecessarily burdensome.

II. Summary of the issues raised by the public comments in response to the Initial Regulatory Flexible Analysis:

There were no comments submitted in response to the Initial Regulatory Flexible Analysis.

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[7] Although MR systems operate on frequencies that include television channels 2 and 3, MSTV states that "it would not appear that MR devices, standing alone, are likely to cause significant interference with broadcast television operations." MSTV comments at 2.

[8] In addition, Sections 18.105, 18.109 through 18.119, 18.301 and 18.303 will apply to MR systems. These sections cite other rule parts relating to the authorization and operation of ISM equipment; general technical operating and importation requirements; and frequencies available for ISM use. Although the Notice did not specifically propose to apply Section 18.301 to MR systems and other Part 18 exempt equipment, it is obvious that Section 18.301 in fact does apply because it specifies the frequencies on which ISM equipment may operate. Accordingly, we are amending Section 18.121, which specifies the requirements for exempt equipment, to make this clear.

III. Significant alternatives considered.

The Commission has considered retaining the existing rules; however, in adopting these changes we are ensuring that our regulations do not unduly burden the industry and at the same time are providing adequate protection to the other users of the spectrum.

ORDERING CLAUSES

11. Accordingly, **IT IS ORDERED** that pursuant to the authority contained in Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, Part 18 of the Communications Rules and Regulations **IS AMENDED** as set forth in the Appendix below. These Rules and Regulations are effective [30 days after publication in the Federal Register]. **IT IS FURTHER ORDERED THAT** this proceeding **IS TERMINATED**.

12. For further information on this proceeding, contact Errol Chang, Technical Standards Branch, Office of Engineering and Technology, telephone 202-653-7316.

FEDERAL COMMUNICATIONS COMMISSION

William F. Caton
Acting Secretary

APPENDIX

Part 18 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 18 - INDUSTRIAL, SCIENTIFIC, AND MEDICAL EQUIPMENT

1. The authority citation for Part 18 continues to read as follows:

AUTHORITY: 47 U.S.C. 4, 301, 302, 303, 304, and 307.

2. Section 18.107 is revised by adding a new paragraph (j) to read as follows:

Section 18.107 Definitions.

* * * * *

(j) Magnetic resonance equipment. A category of ISM equipment in which RF energy is used to create images and data representing spatially resolved density of transient atomic resonances within an object.

3. Section 18.121 is revised to read as follows:

Section 18.121 Exemptions.

Non-consumer ultrasonic equipment, and non-consumer magnetic resonance equipment, that is used for medical diagnostic and monitoring applications is subject only to the provisions of Section 18.105, Sections 18.109 through 18.119, Section 18.301 and Section 18.303 of this Part.